TSCB (Sec 18)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 6/18/96

SUBJECT: ID#96AZ0011. SECTION 18 EXEMPTION FOR THE USE OF **MYCLOBUTANIL** ON **WATERMELONS** IN THE STATE OF **ARIZONA.**

DP Barcode:	D226734	Caswell:	723K
Trade Name:	Rally 40W	Chem#:	128857
Reg#:	707-215	Case#:	287842
Class:	Fungicide	40 CFR:	180.443

TO: D. Deegan/M. Johnson, PM Team 41
ERMUS/RSB/RD (7505W)

FROM: M. Nelson, W. Dykstra, T. Manville
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)

THRU: Michael S. Metzger, Acting Chief
RCAB/HED (7509C)

INTRODUCTION

The Arizona Department of Agriculture is proposing a §18 crisis exemption for the use of myclobutanil on watermelons for control of powdery mildew. This is the first §18 request for this use. The proposed program is limited to Yuma County only, and will entail application of 1275 lbs (510 lbs ai) of Rally 40W Agricultural Fungicide in Water-Soluble Pouches (EPA Reg. No. 707-215) to 850 acres during the period 5/24/96 - 7/15/96.

RECOMMENDATION

Occupational exposure and dietary risk estimates do not exceed HED's level of concern. **Provided the Section 18 label is revised so the restricted entry interval is 48 hours,** HED has no objection to the issuance of this Section 18 exemption for the use of myclobutanil on watermelons in the State of Arizona. An agreement should be made with FDA regarding the legal status of the treated watermelons in interstate commerce.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

   a) Short-Term Risk. For short-term dermal MOE calculations, the TES Committee recommended use of the systemic NOEL of 100 mg/kg/day from the 21-day dermal toxicity study in rats (MRID# 00266080). This dose level was the highest tested in the study. The TES Committee did not identify an inhalation endpoint.

   b) Intermediate-Term Risk. For intermediate-term MOE calculations, the TES Committee recommended use of the NOEL of 10 mg/kg/day from the 2-generation rat reproduction study (MRID#s 00143766, 00149581). At the LEL of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in number of stillborns, and atrophy of the prostate and testes.

   c) Chronic Risk. For chronic MOE calculations, the TES Committee did not recommend a study, and there is no chronic exposure scenario with this §18 action.

   d) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee as a Group E chemical - "evidence of non-carcinogenicity for humans".

2. Dietary Endpoint Selection

   a) Acute Risk. The TES Committee has not identified an acute dietary toxicological endpoint.

   b) Chronic Risk. The RfD of 0.025 mg/kg/day was established by the RfD/Peer Review Committee based on the chronic feeding study in rats (MRID#s 00149582, 00165247) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100 based on testicular atrophy at the LEL of 9.9 mg/kg/day.

   c) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee as a Group E chemical - "evidence of non-carcinogenicity for humans".

Occupational Exposure

1. Acute data for this formulation are available to PIRAT. The proposed work clothing and personal protective equipment (PPE) listed on the label (long-sleeved shirt, long pants, water proof gloves, shoes plus socks, eyewear, and chemical-resistant headgear for overhead exposure) are in compliance with the Worker Protection Standard (WPS).

2. Acute toxicological data for the technical are as follows: category I for primary eye irritation; category III for acute oral and dermal LD50; category IV for primary dermal irritation and acute oral LD50. The restricted entry interval (REI) of 24 hours appearing on the label is not in compliance with the WPS. **To be in compliance with the WPS, the Section 18 label should specify an REI of 48 hours.**

3. Short- and intermediate-term worker margins of exposure (MOEs) are estimated to be below HED's level of concern because the toxicological endpoints selected are NOELs of 100 mg/kg/day and 10 mg/kg/day, respectively, and the worker exposure is minimal due to the product formulation (in water-soluble bags), low application rate, the small total acreage involved, and the relatively high finish spray volumes.

Dietary Exposure

1. The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).

2. An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID# 408033-02, quantitation is by GLC using an N/P detector for myclobutanil and an EC detector for residues measured as the alcohol metabolite) is available to enforce the tolerance expression. A copy is on file in PP#4E4302.

3. Combined residues of myclobutanil plus its alcohol metabolite in watermelon are **not expected to exceed 0.3 ppm** as a result of this Section 18 use.

4. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

5. Since myclobutanil is classified as a Group E chemical, Delaney considerations do not apply.

6. Dietary exposure estimates for myclobutanil are discussed below and a copy of the chronic DRES analysis (6/11/96) is attached.

   a) Acute Dietary Risk. Not estimated; the TES Committee has not identified an acute dietary toxicological endpoint.

   b) Chronic Dietary Risk. Published myclobutanil tolerances plus the proposed §18 use result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to 16.5% of the RfD for the US general population (48 states) and 98.2% of the RfD for the highest exposed population subgroup, non-nursing infants (<1 year old).

The Incremental Dietary Risk from this §18 use is <0.1% of the RfD for the US general population (48 states) and <0.02% of the RfD for the highest exposed population subgroup, non-nursing infants (<1 year old).

c) Dietary Cancer Risk. Not estimated; myclobutanil is classified as a Group E chemical.

d) Anticipated Residues. Not required; the TMRCs (based on the published tolerances plus the proposed §18 use) do not exceed 100% of the RfD for any population subgroup.

SUPPLEMENTAL INFORMATION

Dietary Exposure

Table 1. Residue Considerations Summary Table

PARAMETER	PROPOSED USE	COMPARISON RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W (EPA Reg. No. 707-215) (packaged in water-soluble pouches)	Rally 40W (EPA Reg. No. 707-215) (packaged in water-soluble pouches)
CROP	Watermelon	Cantaloupe
TYPE APPLICATION	Foliar, by ground (full coverage) or air (≥10 gpa). Do not apply by chemigation.	Ground - full coverage foliar spray
# APPLICATIONS	≤ 6	6-7
TIMING	Begin at first sign of disease and continue on a 7-10 day schedule. Applications may be made up to day of harvest.	Began with onset of disease and was repeated at 6-12 day intervals (CA; MD not specified) until 0-7 days before harvest.
RATE/APPLICATION	0.25 lb (0.1 lb ai)/A	0.063 lb ai/A (MD); 0.063/0.125 lb ai/A (CA)
RATE/SEASON	≤ 1.5 lbs (0.6 lb ai)/A	0.441 lb ai/A (MD); 0.378/0.75 lb ai/A (CA)
MAXIMUM RESIDUE	N/A	**0.19 ppm.** Cantaloupe (7 x 0.063 lb ai/A = 0.441 lb ai/A, 3/4X label seasonal max), 0- & 5-day PHIs, MD, 86-0369).
RESTRICTIONS	Yuma County only. Follow §3 registered label's rotational crop restrictions.	Do not exceed 1.5 lbs (0.6 lb ai)/A/crop. Follow label rotational crop restrictions.
RESIDUE DATA SOURCE	N/A	MRID# 410855-01 (MD/cantaloupes/86-0369) MRID# 421890-01 (CA/cantaloupes/90-0128 and 90-0123) (Both reviewed re PP#s 9G3765 and 2F4155)
PERFORMING LAB	N/A	Rohm and Haas Co., Spring House, PA

Attachment: Chronic DRES Analysis (6/11/96)

cc (with Attachment):

M. Nelson
PIRAT
SAB (B. Steinwand)

cc (without Attachment):

T. Manville	OREB (#128857)
W. Dykstra	Caswell File (#723K)
CBTS (§18)	TOX I (P. Hurley)

RDI:PIRAT:6/18/96 **[mjn file: MYCL-WAT.S18]**